



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/593,437

09/18/2006

David Peter Shaw

PL10-003

9878

21567 7590 04/15/2009
WELLS ST. JOHN P.S.
601 W. FIRST AVENUE, SUITE 1300
SPOKANE, WA 99201

EXAMINER

D ABREU, MICHAEL JOSEPH

ART UNIT

PAPER NUMBER

3762

MAIL DATE

DELIVERY MODE

04/15/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/593,437	Applicant(s) SHAW, DAVID PETER	
	Examiner Michael D'Abreu	Art Unit 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 January 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3-6,8-10 and 12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3-6,8-10 and 12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This Office action is responsive to communications filed on 21 January 2009.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. Claims 3-6, 8-10, & 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Terry, Jr. et al. (USP# 5,335,657; hereinafter "Terry") in view of Benser et al.(USP# 7,421,296; hereinafter "Benser").

4. Regarding Claims 3-5, 8-10, & 12, Terry discloses a method of providing sleep apnoea treatment or therapy (e.g. Abstract) through an apparatus in close proximity of the vagus nerve (e.g. Col 9, line 50 – Col 10, line 3; Fig. 2A) which indirectly stimulates

Art Unit: 3762

the respiratory centre of the brain by synchronizing EEG activity (e.g. Col 11, line 55 – Col 12, line 4) via electrical stimulation of the afferent vagal nerve (e.g. Col 6, lines 45-55). Terry further specifies that the stimulation may be in response to a condition detected from a thoracic impedance sensor (e.g. Col 13, lines 28-54; Fig 6B) and that the apparatus can be implanted within the patient (e.g. Col 7, line 65 - Col 8, line 14) or located externally (e.g. Col 13, lines 55-63).

5. Terry fails to specify the direct stimulation of the phrenic nerve; however, it is well known in the art that the afferent phrenic nerve directly stimulates the respiratory centre. Benser discloses that the phrenic nerve can be used to measure the central respiratory drive (e.g. Col 9, lines 42-54). It would have been obvious to one of ordinary skill in the art to modify the method of Terry by simply substituting the afferent phrenic nerve for the vagus nerve during stimulation in order to provide the predictable results of aiding the patient in breathing by directly stimulating the respiratory centre so as not to cause side effects through indirect stimulation. In addition, it would have been obvious to one having ordinary skill in the art to try different pathways for respiratory stimulation to provide the predictable results of using a known technique to provide an alternate stimulation pathway for effectively treating the patient.

6. With regard to Claim 6, Terry discloses the claimed invention except for specifying the diameter of the nerves to be stimulated. It would have been obvious to one having ordinary skill in the art at the time the invention was made to stimulate the afferent fibers within the range of 12-20 micrometers, since it has been held that where

Art Unit: 3762

the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Response to Arguments

7. Applicant's arguments, filed 21 January 2009, with respect to the rejection(s) of claim(s) 3-6, 8-10, & 12 under Libbus et al. (US 2005/0288729) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Terry, Jr. et al. (USP# 5,335,657).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael D'Abreu whose telephone number is (571)270-3816. The examiner can normally be reached on Monday - Friday, 0600 - 1630 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3762

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/M. D./
Examiner, Art Unit 3762

/George R Evanisko/
Primary Examiner, Art Unit 3762